

REMARKS/ARGUMENTS

The Examiner indicates that claims 1, 3, 5 to 13 and 17 to 32 are pending in the application. However, Applicant wishes to clarify that in light of the cancellation of claims 20 and 23 in the Response of January 13, 2006, and the cancellation of claims 17 to 19 in the Response of May 19, 2004, claims 1, 3, 5 to 13, 21, 22 and 24 to 32 are presently pending. Confirmation in this respect is respectfully requested.

There remain 23 claims pending.

Rejections under 35 USC §112, 2nd paragraph

Claims 1, 3, 5 to 13, 21, 22 and 24 to 32 stand rejected as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter, which Applicant regards as the invention. More specifically, the Examiner asserts that claim 1 is unclear as to whether:

- the medium comprising the DNA in step (c) also contains the meristematic tissue in step (a);
- the root in step (b) is the same as the meristematic tissue in step (a) or are they in two separate containers;
- the root of step (b) is also exposed to low amperage current; and
- the (+) lead of step (b) is removed before the (-) lead of step (c) is applied.

Claim 1 has been amended for greater clarity. The first and second issues raised by the Examiner have been addressed in that step (b) now specifies that "a the root of the leguminous plant" is suspended in buffer and step (c) now specifies "the medium comprising DNA in step (a)".

Applicant respectfully submits that claim 1 is definite in regard to the remaining issues. On the issue of claim interpretation, the Courts have stated that "those skilled in the art would understand what is claimed when the claim is read in light of the specification" [Emphasis added] *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986). On this basis, a claim must not be considered as an isolated statement but must be interpreted by reading the patent as a whole, that is, in the light of the specification and with due regard to the wording

of the claims. It must be considered in light of the knowledge which an intelligent person skilled in the art would possess and with the motivation of a person willing to understand and desirous of making use of the invention.

Accordingly, Applicant respectfully submits that the claims are definite and in this respect, requests that the rejections be withdrawn.

Rejections under 35 USC §112, 1st paragraph

Claims 1, 3, 5 to 13, 21, 22 and 24 to 32 stand rejected for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the Applicant, at the time the application was filed, had possession of the claimed invention. Applicant respectfully traverses the rejection and submits that "leguminous plants" is supported in the application as originally filed.

The test for determining compliance with the written description requirement is whether the disclosure of the application, as originally filed, reasonably conveys to the skilled person that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language (see *Vas-Cath, Inc. v. Makurkar*, 935 F.2d 1555, 1563-64 and *In re Kaslow*, 707 F.2d 1366, 1375). In applying this test to the instant case, Applicant respectfully submits that the claim amendment is implicitly disclosed and supported by the original disclosure of the instant application. A "leguminous plant" is a plant having a pod containing dry seeds, which includes soybeans and drybeans. These plants are supported in the application as originally filed, for example, at page 6, lines 7 to 8:

... [E]xamples of such plants include, but are not limited to, dry bean, soybean, corn, barley, cucumber and cotton.

Accordingly, a skilled person would recognize that the Applicant was in possession of the invention as claimed and that the claim amendment does not add information that goes beyond the subject matter as originally filed (see also, for example, page 6, lines 6 to 7). The specification as originally filed, supports dicots and monocots, two broad groups of flowering

plants; leguminous plants are dicots. Accordingly, the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as presently claimed.

In the absence of evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the claimed invention, Applicant submits that the claims satisfy 35 USC §112, 1st paragraph.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Rejections under 35 USC §103

Claims 1, 3, 5 to 13, 21, 22 and 24 to 32 stand rejected for allegedly being obvious and unpatentable over Burchi *et al.* in view of one or the other of Bidney *et al.* (U.S. Patent No. 6,166,291), Griesbach and Vik *et al.* Applicant respectfully traverses the rejections.

Burchi *et al.* disclose preliminary results of transient GUS gene expression in axillary shoots of carnation, chrysanthemum and lisianthus transformed *in vivo* by the electrotransfection method. After the test plants were grown in pots to an appropriate stage of development, a platinum wire connected to the anode was inserted into the soil in contact with the roots (see page 164, 1st column, last paragraph). Only about 50% of the treated plants survived and about 50% of those plants which survived showed transient GUS expression. The poor survival rate of the plants has been attributed primarily to mineral toxicity effects caused by an increased uptake of positively charged ions from the soil to the roots of the plant following electrophoresis.

In contradiction to this teaching, the Examiner states:

Burchi teaches a method for transforming a plant ... suspending a root of the plant in buffer and contacting said root with a lead of a power source ... Burchi does not teach the positive lead in the soil/root medium, a "leguminous plant" nor "T-DNA region and border sequences". [Emphasis added.]

Applicant respectfully submits that the Examiner's reading of the Burchi reference is misplaced because the disclosure does teach suspending a root of the plant root in soil, and not buffer as

stated. Therefore, Burchi does not teach (1) the positive lead in buffer, (2) a leguminous plant, and (3) T-DNA region and border sequences.

Bidney et al. (U.S. Patent No. 6,166,291) disclose a method of producing a pathogen resistant hybrid plant using explants cocultivated with *Agrobacterium* to facilitate DNA delivery. The soybean transgenics (at column 36, Example 3), were produced in accordance with the protocol described in U.S. Patent No. 5,563,055 (hereinafter referred to as the '055 patent).

The protocol described in the '055 patent involves the co-culture of soybean explants with *Agrobacterium* species carrying a plasmid into which is inserted the gene of interest. *Agrobacterium*-mediated transformation involves the co-cultivation of the explant with an *Agrobacterium* species having a "binary" tumor-inducing (Ti) plasmid vector system comprising: (1) a Ti-plasmid which carries a single-stranded copy (T-strand) of the bacterial tumor-inducing DNA (T-DNA) (and into which is inserted the gene or genes of interest); and (2) a "helper" plasmid that encodes specific *Agrobacterium* virulence proteins (Vir) essential for T-DNA transfer as they associate directly with the T-strand to form a transport complex (T-complex). Nuclear import of the T-complex culminates with T-DNA integration into the host genome. Since the T-DNA molecule itself does not contain specific signals for nuclear import, T-DNA insertion into the plant DNA must be mediated by proteins transported from *Agrobacterium* itself. Vir proteins of the T-complex have been implicated in the integration process. Thus, the genetic transformation is achieved by bacterial attachment to the plant cell surface, transfer of T-DNA from bacteria to plant cells across the plant wall and membrane, nuclear transport of the T-complex, and stable integration of T-DNA into the plant genome. These events involve direct interactions between plant proteins and *Agrobacterium* virulence (Vir) proteins that are exported to the plant and accompany the T-DNA on its journey through the plant cell to the nucleus.

The role of the Vir proteins in facilitating T-DNA transfer is further supported at column 2, line 50 of the '055 patent, where it states:

Several factors which significantly impact the transformation of cultured soybean cells have been identified in arriving at this invention. The most important of these appears to be the induction of the virulence (vir) genes in *Agrobacterium* by

proper use of signal molecules during cocultivation. Cultured soybean cells lack or have a limiting amount of the necessary signal molecules to initiate the transformation process.... This invention uses acetosyringone, a phenolic compound produced by wounded plant cells, to induce the vir genes. [Emphasis added.]

Further, at column 3, line 23 of the '055 patent, it states:

The successful transformation of soybean cells was also dependent upon the concentration of bacteria in the inoculum. In general, higher numbers of bacteria resulted in more transformation events.

In contrast, the instant application teaches a method of transformation using a mature intact plant or seedling and a single plasmid. No where in the description or the examples is the invention described or claimed as employing (1) an explant, (2) a "binary" system that necessitates the use of a "helper" plasmid that encodes specific *Agrobacterium* virulence (Vir) proteins, and/or (3) co-cultivation of the explant with *Agrobacterium*.

Vik et al. was published in 2001. Applicant respectfully submits that the *Vik et al.* reference is not citable under 35 USC §103 which concerns information that was available to the public at the time the invention was made. Because the publication date of the *Vik et al.* reference (i.e. 2001) is after the filing date of the instant application (i.e. December 8, 1998), the information was not publicly available and therefore, the reference is not citable and withdrawal of the rejection is required.

Griesbach teaches electrophoretic transformation of orchid embryos or protocorms. Fig. 1 at page 82 illustrates the electrophoretic apparatus used to transfer DNA in which a protocorm is placed between two pipette tips. The tips are both filled with electrophoretic buffer and one containing DNA in agarose is connected to the negative terminal of a power source while the other containing DNA-free agarose is connected to the positive terminal. The apical meristem of the protocorm is in contact with the negative tip and the basal region of the protocorm is in contact with the positive tip. It further states that the protocorms are subjected to electrophoresis in a dry state.

Applicant respectfully submits that neither Burchi *et al.*, Bidney *et al.* nor Griesbach teach or suggest all of the elements and limitations recited in the claims.

Secondly, there is no suggestion, teaching or motivation to combine the references on which the rejection is based. Neither of the prior art references suggest any desirability to combine the elements as claimed for transforming a plant using electrophoresis and DNA comprising a plasmid vector.

Thirdly, a person of skill in the art would not have any reasonable expectation of success that the combination of Burchi *et al.*, Bidney *et al.* and/or Griesbach would work to arrive at the claimed invention through a minimum of experimentation. Burchi *et al.* teach a DNA transfer method using electrophoresis in which the cathode was placed on the meristem and the anode was inserted into the soil in close contact with the roots of the plant. Bidney *et al.* disclose a method of producing a soybean transgenic plant in which a soybean explant was co-cultivated with *Agrobacterium* species having a "binary" tumor-inducing (Ti) plasmid vector system to facilitate DNA delivery. Griesbach teaches electrophoretic transformation of orchid embryos or protocorms in a dry state.

Based on the combined teachings of these references, it is therefore asserted that a skilled artisan would have absolutely no reasonable expectation of success that an intact plant having the root suspended in buffer could be transformed with DNA by applying a low amperage current as described in the instant application.

To assist the Examiner in understanding the principles of *Agrobacterium*-mediated gene transfer, Applicant submits copies of three references of interest which are listed in the Appendix attached herewith. These references show that tumorigenesis induced by *Agrobacterium* infection is a key process for the transfer of genetic material from the bacteria to the plant. No where in these references, or in the prior art in general, is it demonstrated that T-DNA transfer is facilitated in the absence of *Agrobacterium* co-cultivation. In other words, there is no scientific evidence to show that a single Ti-plasmid, as used in the instant application, performs differently to any other plasmid used in current plant transformation methods involving electrophoresis.

In summary, Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness based on these references.

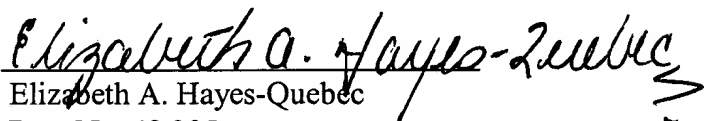
Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

The Examiner is respectfully urged to call the undersigned at (613) 232-2486 to discuss the claims in an effort to reach a mutual agreement with respect to claim limitations in the present application which will be effective to define the patentable subject matter if the present claims are not deemed to be adequate for this purpose.

In view of the forgoing, early favorable consideration of this application is earnestly solicited.

Respectfully submitted,

Richard F. Allison, et al

By 
Elizabeth A. Hayes-Quebec
Reg. No. 48,305
Tel.: (613) 232-2486 ext. 208

Date: August 18, 2006

EAH:pw

APPENDIX

References of Interest

1. Zupan, *et al.*, *Transfer of T-DNA from Agrobacterium to the Plant Cell*. Plant Physiol. (1995) 107: 1041-1047.
2. Zupan, *et al.*, *The transfer of DNA and Agrobacterium tumefaciens into plants: a feast of fundamental insights*. The Plant Journal (2000) 23(1): 11-28.
3. Gelvin, Stanton B., *Agrobacterium and Plant Genes Involved in T-DNA Transfer and Integration*. Annu. Rev. Plant Physiol. Plant Mol. Biol. (2000.) 51:223-56